



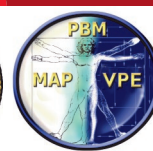
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VA Center for Medication Safety

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Medication *safety in seconds*

A MONTHLY PUBLICATION FROM VA MEDSAFE:
VA'S COMPREHENSIVE PHARMACOVIGILANCE CENTER

Helping to achieve safe medication use

FENTANYL (DURAGESIC®) TRANSDERMAL SYSTEMS: ACCIDENTAL OPIOID EXPOSURE DUE TO IMPROPER DISPOSAL

Fentanyl (Duragesic®), a schedule II opioid used for the management of persistent, moderate to severe chronic pain, has an associated risk for fatal overdose due to respiratory depression. Accidental exposure to fentanyl (Duragesic®) transdermal patches continues to cause potential harm and death, especially in children. On April 18, 2012, the Food and Drug Administration (FDA) issued an alert to remind providers, patients, and caregivers of this danger based on 26 reports of pediatric accidental exposures to fentanyl (Duragesic®) patches received over the past 15 years: 16 occurred in children 2 years old and younger; 12 lead to hospitalizations; and 10 resulted in death. The National Medication Errors Reporting Program operated by the Institute of Safe Medication practices also released a NAN alert (National Alert Network) on April 25, 2012, to raise awareness that incidents of pediatric accidental exposures can occur outside the home in the setting of a health care institution where children may accompany adults visiting patients. One case involved the death of a 2-year old boy who ingested a portion of a used fentanyl (Duragesic®)

patch still containing a high concentration of active drug while visiting a relative in a nursing home. Further investigation at the facility uncovered staff's improper disposal of patients' used medication patches, with used fentanyl (Duragesic®) patches found on the bedside table, trash can, floor, and stuck to bed railings.

Increased awareness and proper disposal of fentanyl (Duragesic®) patches can help prevent accidental exposure, drug-related symptoms, and death, especially to children, who may think of the transdermal systems as band-aids or stickers.

Health care staff administering/applying fentanyl (Duragesic®) transdermal systems in a health care facility should practice safe disposal of used patches as described in product labeling:

- "... fold the sticky sides of a used DURAGESIC® patch together and flush it down the toilet. Do not put used DURAGESIC® patches in a trash can. "

(continued on page 2)



Safety matters

NEWS YOU CAN USE

FROM THE VA NATIONAL PBM: BULLETINS, COMMUNICATIONS, & RECALLS

- Citalopram (Celexa®) and Dose-Dependent QT Interval Prolongation: UPDATED RECOMMENDATIONS - [National PBM Bulletin](#) – 04-17-2012



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NEWS YOU CAN USE

FROM THE FOOD AND DRUG ADMINISTRATION (FDA)

INFECTIOUS DISEASES

[Updated information on drug interactions between Victrelis \(boceprevir\) and certain boosted HIV protease inhibitor drugs](#)

04/26/2012 (** UPDATE FROM 02/04/2012**)

FDA does not recommend co-administration of boceprevir (Victrelis®) with ritonavir-boosted atazanavir (Reyataz®), ritonavir-boosted darunavir (Prezista®), or lopinavir/ritonavir (Kaletra®) to patients infected with both chronic hepatitis C virus (HCV) and human immunodeficiency virus (HIV). The combination can reduce the effectiveness of the drugs, allowing an increase in HCV or HIV viral load as suggested from findings of 2 studies:

- A drug-drug interaction study, which showed that taking Victrelis while taking any one of the three ritonavir-boosted HIV protease inhibitors could reduce the desired blood levels of both medicines; and
- A small clinical trial that measured treatment outcomes of HIV-HCV co-infected patients whose HCV infection was treated with either peginterferon/ribavirin or boceprevir plus peginterferon/ribavirin and whose HIV infection was treated with ritonavir-boosted atazanavir, ritonavir-boosted darunavir, lopinavir/ritonavir, or raltegravir (Isentress®). Persons who received boceprevir plus peginterferon/ribavirin had higher rates of undetectable HCV viral loads 12 weeks post-HCV treatment than those on peginterferon/ribavirin alone.

CARDIOLOGY

[New Warnings and Contraindication for blood pressure medicines containing aliskiren](#)

04/20/2012

A new warning advises avoidance of aliskiren with angiotensin receptor blockers (ARBs) or angiotensin-converting enzyme inhibitors (ACEIs) in patients with moderate to severe renal impairment (i.e., where glomerular filtration rate [GFR] < 60 mL/min). Revisions to the aliskiren labels are based on preliminary findings from the ALTITUDE trial. Prior to this alert, the FDA had already contraindicated use of aliskiren with ARBs or ACEIs in patients with diabetes because of the risk of renal impairment, hypotension, and hyperkalemia (see earlier VA-specific recommendations at [National PBM Bulletin](#)).

WOMEN'S HEALTH

[Updated information about the risk of blood clots in women taking birth control pills containing drospirenone](#)

04/10/2012 (** UPDATE FROM 10/27/2011**)

FDA completed its review of recent epidemiologic studies evaluating the association of blood clots with drospirenone-containing oral contraception and concluded that birth control medications containing drospirenone may confer a higher risk for blood clots compared to progestin-containing medications. However, studies reviewed did not provide consistent estimates of comparative risk or take into account patient risk factors for developing blood clots. Revisions to product label will reflect that studies found a range of as low as no additional risk to as high as a 3-fold increase in risk for blood clots associated with drospirenone-containing products compared to those containing levonorgestrel or progestins.

Helping to achieve safe medication use

FENTANYL (DURAGESIC®) TRANSDERMAL SYSTEMS: ACCIDENTAL OPIOID EXPOSURE DUE TO IMPROPER DISPOSAL

(continued from page 1)

Health care providers should educate patients prescribed medication patches and their caregivers on the proper storage and disposal of medication patches as well as the hazards associated with new and used medication patches, specifically:

- *Store in original unopened pouch.*
- *Keep a DURAGESIC® patch in its protective pouch until you are ready to use it.*
- *Keep DURAGESIC® in a safe place out of the reach of children and pets.*
- *Dispose of DURAGESIC® patches you no longer need. Open the unused packages, fold the sticky sides of the patches together, and flush them down the toilet.*
- *When you remove your DURAGESIC® patch, fold the sticky sides of a used DURAGESIC® patch together and flush it down the toilet. Do not put used DURAGESIC® patches in a trash can.*

Pharmacy should consider adding proper disposal instructions to the prescription label when prescriptions for fentanyl (Duragesic®) transdermal systems are ordered and dispensed on an outpatient basis.

Providers should continue to report any adverse drug events with the use of fentanyl (Duragesic®) transdermal systems by entering the information into CPRS' Allergies/ Adverse Reactions field and/or via local reporting mechanisms. Adverse events should also be reported, as appropriate, to the VA ADERS program and FDA MedWatch.

REFERENCES:

1. FDA Drug Alerts and Statements. FDA Reminds the Public about the Potential for Life-Threatening Harm from Accidental Exposure to Fentanyl Transdermal Systems ("Patches"). <http://www.fda.gov/Drugs/DrugSafety/ucm300747.htm>. (Accessed April 25, 2012).
2. NAN ALERT. Proper disposal of fentanyl patches is critical to prevent accidental exposure. National Coordinating Council on Medication Error Reporting and Prevention (NCCMERP): April 25, 2012.
3. DURAGESIS® CII (Fentanyl Transdermal System) [package insert]. Raritan, NJ: Pri-Cara®, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc.; July 2009.

Getting the most from our safety surveillance

NATIONAL MUE CLEARINGHOUSE | A LIFELINE FOR LOCAL SITES

ATTENTION PHARMACISTS:

Caught by the undertow of safety and quality improvement measures? Let PBM's National Medication Utilization Evaluation (MUE) Clearinghouse keep you afloat!

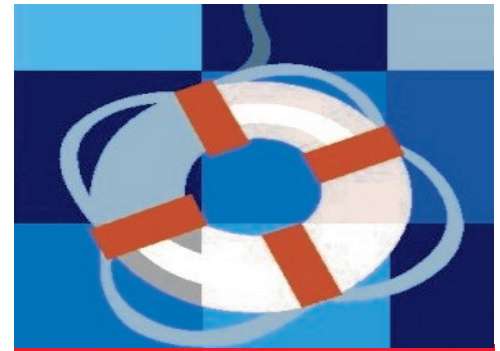
This useful tool facilitates the sharing of information among VA Medical Centers nationwide with respect to local MUE efforts. Each facility can increase their awareness of various medication issues under evaluation in the VA system with the goal of improving medication use processes and optimizing patient outcomes while maintaining standards of care. Sharing details of locally-conducted MUEs can:

- Invite insight from other sites that may have experienced the same or similar medication safety and practice issues and their method for resolution;
- Stimulate discussion among sites on useful approaches to monitor measures of safety and quality, as well as to meet program, provider, and patient goals for issues involving:
 - Medication management;
 - Disease state management; and/or
 - Medication use process management (ordering and transcribing, preparing and dispensing, administration and monitoring).
- Coordinate efforts in:
 - Implementing national medication use policies;
 - Assessing their clinical and operational benefit; and
 - Forecasting services to meet facility/patient needs.

So why struggle with project minutia alone any longer when PBM's National MUE Clearinghouse can bring the collective knowledge of your peers to your fingertips?

We welcome each site to take advantage of this shared opportunity and exchange of information for ongoing and/or completed MUEs.

NOTE: As with other data entry mechanisms, input equals output, so the more specifics included, the greater the value!



WE VALUE YOUR PARTICIPATION!

HOW TO ENTER LOCAL MUE INFORMATION

- For VISN-Wide MUEs, visit:
<http://vaww.national.cmop.va.gov/PBM/medsafe/VISNWide%20MUEs>
- For Local Facility MUEs, visit:
<http://vaww.national.cmop.va.gov/PBM/medsafe/Local%20Facility%20MUEs>
- Post information in 3 quick and easy steps:
 1. Click on the link
 2. Upload document
 3. Save and Close
- Please ensure compliance with privacy and security rules.
- For questions and suggestions, please contact:
Muriel.Burk@va.gov.